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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/980,211	01/30/2002	Klaus Schumann	3868-0103P	9968

2292 7590 06/03/2005

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EXAMINER	
GHALI, ISIS A D	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 06/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/980,211	SCHUMANN ET AL.	
	Examiner	Art Unit	
	Isis Ghali	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 March 2005* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11-14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

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DETAILED ACTION

The receipt is acknowledged of applicants' amendment after final, filed 02/11/2005; and request for RCE, filed 03/23/2005.

Claims 11-14 are included in the prosecution.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 03/23/3005 has been entered.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 11 recites a method of preventing pressure-sensitive adhesive (PSA) from leaking out in cold flow during storage of PSA-substrate that sealed in a bag to protect against loss of active substance, the substrate comprising backing, matrix of PSA or provided with PSA layer on its application surface, the method comprising the step of providing a detachable carrier layer on the PSA made of two sections that are overlapping and is larger than the PSA layer. One of the carrier layer sections is wider than the other by an amount of overlap (claim 12). One of the carrier layer sections is wider than half the width dimension of an undivided carrier layer by the amount of half the overlap (claim 13); and the region of the overlap is positioned centrally or eccentrically (claim 14).

4. Claims 11-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,626,866 ('866) in view of WO 96/34633 ('633).

US '866 teaches a transdermal drug delivery device or patch to deliver volatile drugs comprising a backing layer, a drug-containing layer or reservoir of pressure sensitive adhesive and a peelable release liner (abstract; col.1, lines 10-12; col.3, lines 48-49; col.8, lines 30-37). The release liner formed of two stripes that overlap in the center for protecting the adhesive reservoir and retaining the drug in the device and also

for easy peeling of the release liner upon use (col.12, lines 17-27). The patch is sealed in a pouch (col.12, lines 32-33). Figure 4 shows that one carrier section is wider than the other by the amount of the overlap (claim 12). It is also expected that if we have a carrier layer and divide it into two pieces and partially overlap the two pieces on top of each other, it is expected to have shorter width of the overlapped sections than the undivided carrier. Thus, in order to have the overlapped carrier sections having same width of the undivided carrier layer we have to increase the width by the amount of the overlap and this increase can be added on one side or divided on both sections of the carrier, and in the later situation it will give half the amount of overlap on each side (claim 13). In any events, applicants are not claiming any dimensions of the carrier layer sections or the overlapping portions that impart patentability to the claims.

US '866 does not teach that the carrier layer or the two parts of the release liner project partially beyond the matrix.

WO '633 teaches a dressing set comprising a backing; a reservoir containing at least one pharmaceutically active substance; and more than one peel stripes to protect the reservoir (abstract; page 2, last paragraph). The peel stripes extend beyond the edges of the dressing and are overlapping (page 4, paragraph 3, Figure 2).

Accordingly, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide a transdermal device having PSA reservoir layer protected by release liner made of two overlapping sections as disclosed by US '866, and replace the release liner by the carrier layers having two overlapping sections that extend beyond the reservoir layer as disclosed by WO '633, motivated by the

teaching of WO '633 that the extended overlapping carrier layer provides protection of the reservoir, as desired by applicants, with reasonable expectation to achieve a transdermal device comprising PSA layer covered by carrier layer with two overlapping sections that extend beyond the reservoir layer for more protection of the adhesive and the contained drugs.

5. Claims 11-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,626,866 ('866) in view of US 5,044,372 ('372).

US '866 teaches a transdermal drug delivery device or patch to deliver volatile drugs comprising a backing layer, a drug-containing adhesive layer or reservoir of pressure sensitive adhesive and a peelable release liner (abstract; col.1, lines 10-12; col.3, lines 48-49; col.8, lines 30-37). The release liner formed of two stripes that overlap in the center for protecting the adhesive reservoir and retaining the drug in the device and also for easy peeling of the release liner upon use (col.12, lines 17-27). The patch is sealed in a pouch (col.12, lines 32-33). Figure 4 shows that one carrier section is wider than the other by the amount of the overlap (claim 12). It is also expected that if we have a carrier layer and divide it into two pieces and partially overlap the two pieces on top of each other, it is expected to have shorter width of the overlapped sections than the undivided carrier. Thus, in order to have the overlapped carrier sections having same width of the undivided carrier layer we have to increase the width by the amount of the overlap and this increase can be added on one side or divided on both sections of the carrier, and in the later situation it will give half the amount of overlap on each side

(claim 13). In any events, applicants are not claiming any dimensions of the carrier layer sections or the overlapping portions that impart patentability to the claims.

US '866 does not teach that the carrier layer or the two parts of the release liner project partially beyond the matrix.

US '372 teaches transdermal drug delivery device comprising drug reservoir layer and a protective layer comprising two overlapping parts to protect the reservoir up to the time of use and also to act as removal aid (col.3, lines 65-68). Figures 1 and 4 show that the two parts of the protective layer extend beyond the reservoir layer.

Accordingly, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide a transdermal device having PSA reservoir layer protected by release liner made of two overlapping sections as disclosed by US '866, and replace the release liner by the protective layer having two overlapping parts that extends beyond the reservoir layer as disclosed by US '372, motivated by the teaching of US '372 that the extended overlapping carrier layer provides protection of the reservoir and acts as removal aid, as desired by applicants, with reasonable expectation to achieve a transdermal device comprising PSA layer covered by protective layer with two overlapping sections that extend beyond the reservoir layer for more protection of the adhesive and the contained drugs as well as easy removal.

6. Claims 11-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,626,866 ('866) in view of US 6,277,401 ('401).

US '866 teaches a transdermal drug delivery device or patch to deliver volatile drugs comprising a backing layer, a drug-containing adhesive layer or reservoir of pressure sensitive adhesive and a peelable release liner (abstract; col.1, lines 10-12; col.3, lines 48-49; col.8, lines 30-37). The release liner formed of two stripes that overlap in the center for protecting the adhesive reservoir and retaining the drug in the device and also for easy peeling of the release liner upon use (col.12, lines 17-27). The patch is sealed in a pouch (col.12, lines 32-33). Figure 4 shows that one carrier section is wider than the other by the amount of the overlap (claim 12). It is also expected that if we have a carrier layer and divide it into two pieces and partially overlap the two pieces on top of each other, it is expected to have shorter width of the overlapped sections than the undivided carrier. Thus, in order to have the overlapped carrier sections having same width of the undivided carrier layer we have to increase the width by the amount of the overlap and this increase can be added on one side or divided on both sections of the carrier, and in the later situation it will give half the amount of overlap on each side (claim 13). In any events, applicants are not claiming any dimensions of the carrier layer sections or the overlapping portions that impart patentability to the claims.

US '866 does not teach that the carrier layer or the two parts of the release liner project partially beyond the matrix.

US '401 teaches transdermal drug delivery device comprising drug reservoir, adhesive layer, and a release liner of two overlapping parts that protect the adhesive and the drug reservoir during storage (abstract; col.2, lines 10-11, 20-23). Figure 1 b shows that the two parts of the protective layer extend beyond the reservoir layer.

Accordingly, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide a transdermal device having PSA reservoir layer protected by release liner made of two overlapping sections as disclosed by US '866, and replace the release liner by the release liner having two overlapping parts that extend beyond the reservoir layer as disclosed by US '401, motivated by the teaching of US '401 that the extended overlapping release liner parts provide protection of the adhesive and drugs, as desired by applicants, with reasonable expectation to achieve a transdermal device comprising PSA layer covered by protective layer with two overlapping sections that extend beyond the reservoir layer for more protection of the adhesive and the contained drugs.

Response to Arguments

7. Applicant's arguments with respect to claims 11-14 have been considered but are moot in view of the new ground(s) of rejection.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 7:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Isis Ghali
Examiner
Art Unit 1615

IG

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PATENT EXAMINER